Report to Congress

Implementation of Section 3507 of the Patient Protection and Affordable Care Act of 2010

First Progress Report

Food and Drug Administration

March 2011

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Introduction

BACKGROUND

In March 2010, President Obama signed into law a comprehensive health reform bill, the Patient Protection and Affordable Care Act of 2010 , Pub. L. No. 111-148, 124 Stat. 119 (codified at note following 42 U.S.C. § 18001), and a package of amendments to the Affordable Care Act, the Health Care and Education Reconciliation Act of 2010 (HCERA; P.L. 111-152). Section 3507(a)[1] of the Affordable Care Act requires the Secretary of Health and Human Services (HHS), acting through the Commissioner of Food and Drugs, to determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in standardized format (e.g., similar to "Drug Facts" on over-the-counter products) to the promotional labeling or print advertising of such drugs would "improve healthcare decision-making by clinicians and patients and consumers."

The requirements under § 3507(b) direct the Food and Drug Administration (FDA) to consider research in the areas of social and cognitive psychology, and to consult drug manufacturers, clinicians, patients and consumers, specifically "experts in health literacy, representatives of racial and ethnic minorities, and experts in women's and pediatric health."

§ 3507(c) also directs FDA to submit a report to Congress outlining its determination by March 23, 2011. If FDA determines that adding these types of standardized risk/benefit summary statements (or tables) to advertising or promotional labeling for prescription drugs would improve health care decision- making, the Agency has three years from submission of the report to Congress to promulgate proposed regulations setting forth such requirements.

Currently available research does not provide a sufficient scientific basis to support the required determination. FDA estimates that the necessary studies, literature review and consultation with appropriate experts will take roughly three years. These studies are underway and a detailed description and timeline is provided below. If, after these steps are completed, FDA determines that the addition of standardized summary statements would improve health care decision-making, FDA will promulgate proposed regulations within two years of its determination. FDA will provide Congress with annual progress reports detailing the progress that has been made toward fulfilling the requirements of the law, and will report its determination to Congress in the fall of 2013.

Steps and Associated Timeframes for Implementing the Provisions of §3507

To implement the provisions of §3507, FDA will:

- Determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decision-

[1] Pub. L. No. 111-148, § 3507, 124 Stat. 119, 530 (codified at note following 21 U.S.C. § 352).

making by clinicians and patients and consumers. Because currently available research on the communication of quantitative information in prescription drug promotion is not sufficient to support the required determination, the FDA is conducting three studies to address this task.

- Presentation of Quantitative Effectiveness Information to Consumers in Direct-to-Consumer (DTC) Television and Print Advertisements for Prescription Drugs (Quantitative Study). The purpose of this study is to investigate the value of adding quantitative benefit and risk information to DTC advertisements for prescription drugs and to explore a variety of ways to present that information, including numerically and graphically.

- Study of Clinical Efficacy Information in Professional Labeling and Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs (Display Page Study). The purpose of this study is to understand how physicians and consumers make risk/benefit assessments from labeling and advertising and, particularly, how consumers make such judgments in response to variations in the efficacy presentations in the "display" (first) page of a DTC print ad. We will investigate to what extent consumers, when provided with efficacy information, form perceptions that correspond with clinically-based physicians' assessments of the benefits, risks, and benefit/risk tradeoffs of the same drugs.

- Study of Format Variations in the Brief Summary of Direct-to-Consumer (DTC) Print Advertisements (Format Study). The purpose of this study is to systematically examine the type of information that could be presented in a standardized box (i.e., the addition of quantitative and qualitative information in a box format) and the level of efficacy or risk to determine whether and how to add qualitative and quantitative benefit and risk information to the Brief Summary.

We believe that the results from these studies will inform FDA's determination about the usefulness of quantitative summaries of the benefits and risks of prescription drugs in both promotional labeling and print advertising.

- Review all available scientific evidence and research on decision-making and social and cognitive psychology and consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, representatives of racial and ethnic minorities and experts in women's and pediatric health. To do this, FDA will:
  - Hire a contractor to conduct a literature review of these areas.
  - Present the results and this topic generally to the FDA Risk Communications Advisory Committee (RCAC), allowing us to consult with external experts in the field.

- Evaluate potential methods for and the utility of applying a "drug facts box" format for summarizing risks and benefits of products with multiple indications and/or multiple studies. Many products are the subject of multiple pre-market studies conducted by the drug

manufacturer, and the studies may give different, sometimes conflicting, results. Different studies have different strengths and weaknesses. There is currently no clear method for capturing such information in a standardized quantitative summary format. (FDA's overall conclusions about the studies when approving a drug for one or more indications takes into account the relative strengths and weaknesses of the studies, as well as an array of additional information, and does not employ the type of summary contemplated by the legislation.)

Submit to Congress a report that provides (1) the determination by the Secretary under § 3507(a); and (2) the reasoning and analysis underlying that determination.

- If FDA determines that it would improve health care decision-making by clinicians and patients and consumers, it will promulgate proposed regulations for implementing quantitative summaries of Drug Benefit & Risk Information (the content will be determined after completion of research, review of scientific evidence, and consultations with the RCAC and external experts).

Anticipated Products

First Progress Report to Congress	March 2011
Literature Review Timeline	
Current status:	Technical expert review panel selected; Literature review underway.
Completion Date:	November 2011
Study Timelines	June 2010 – September 2012
Quantitative Study	
Current status:	Data analysis underway.
Completion Date:	August 2011
Display Page Study	
Current status:	Under OMB review.
Completion Date:	March 2012
Format Study	
Current status:	60-day Federal Register notice for public comment in progress.
Completion Date:	September 2012
Second Progress Report to Congress	March 2012
Third and Final Progress Report to Congress	March 2013
Analysis and determination; preparation of final summary report	April 2012 – September 2013
Final Summary Report, Evaluation of whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format would improve health care decision-making by clinicians and patients and consumers (including results of studies) submitted to Congress.	September 2013
Promulgate proposed regulations for implementing quantitative summaries of Drug Benefit & Risk Information (dependent upon completion of research, review of scientific evidence, and consultations with the RCAC and external experts).	September 2015

Conclusion

FDA shares Congress' goal of enhancing the public health through improved health care decision-making by clinicians, patients, and consumers. FDA appreciates Congress' recognition that a variety of steps will provide a scientific basis for the appropriate implementation of the requirements of §3507, including a thorough review of all applicable literature, consultation with outside experts in relevant fields, and empirical research. Due to the complexity of the subject and the need for significant research and analysis, the required tasks cannot be completed by March, 2011. This initial progress report lays out the timeline for completing the requirements of the Affordable Care Act and the current status of the work. We will continue to keep the Congress informed of our progress toward implementing this important law.